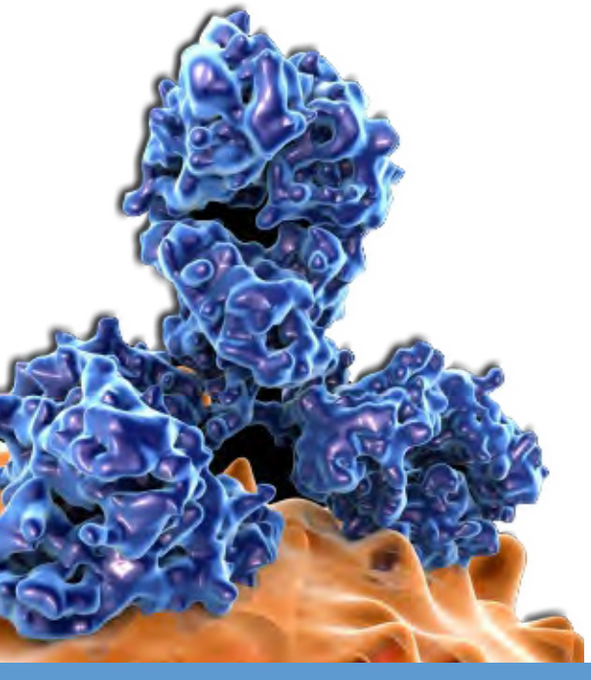
# Accredited Characterisation & QC Testing

ISO 17025

# Biosimilars, biologics, and follow-on therapeutics



*Proposed & reference products*

PILL
Proteomics International

# Technical excellence

## Accredited proteomics laboratory

Quality is Assured

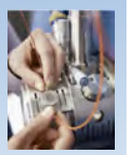
Data analysis conducted at Proteomics International is performed to ISO/IEC 17025 laboratory standard. ISO/IEC 17025 is the most widely used laboratory standard for US Federal testing laboratories, including the FDA's own testing facilities and is recognised worldwide as the main ISO standard used by testing and calibration laboratories.

Proteomics International has been providing analytical services since 2001 and became the world's first facility to receive ISO 17025 accreditation for proteomics services in 2009.

Accreditation ISO/IEC 17025 demonstrates technical competence, therefore laboratories that are accredited to this standard are demonstrating that they follow 'good laboratory practice' and that the data produced is technically valid.

## The most advanced instrumentation available

The laboratory houses a full suite of analysis equipment that delivers greater performance and sensitivity, higher confidence of results and reproducibility and a more comprehensive in-depth identification and relative quantitation of proteins in complex samples.



- 5600 Triple TOF MS, for sensitivity and precision
- 4000 QTRAP MS, for targeted analysis
- 5800 MALDI-TOF/TOF MS, ultra-high throughput
- Prominence nano LC
- Nexera UHPLC
- Ultimate 3000 nano 2D LC system
- Probot micro spotter

## About the Company

Proteomics International is a privately owned company based in Perth, Western Australia. It is located in the Harry Perkins Institute of Medical Research.

The company has established itself as a world leader in developing value specifically from protein based biologics research, biomarker discovery and validation, drug discovery and in the delivery of contract research analytical services, particularly in the areas of biosimilars, biologics and follow on therapeutics.

Proteomics International has been operational for 15 years and has a team of 20 including highly qualified and experienced protein and peptide scientists. For many years Proteomics International has delivered accredited analytical services to a range of blue-chip pharmaceutical companies on a worldwide basis.

Image courtesy of Hames Sharley Architects

# Demonstrating biosimilarity

**Proteomics International will assist you to meet your regulatory requirements for your biosimilar or biologic products.**

**Your stepwise approach for your biosimilar development program begins with extensive structural and functional characterisation of both your proposed product and the reference product to demonstrate biosimilarity. This data underpins all further product development activities and therefore must be done thoroughly and correctly to FDA and ICH guidelines (ICH Q6B).**

## Comprehensive structural and functional characterisation

- **Protein sequence mapping by MS/MS**
  Comprehensive amino acid sequence coverage is obtained by multi-enzyme digest strategies, coupled with multi-instrument approaches. Data analysis incorporates the latest algorithms and includes options for *de novo sequencing*.
- **Di-sulphide mapping**
  Characterising disulphide folding patterns to confirm correct or misaligned bridges, and free or capped cysteine residues. A number of specialist and best- in-class techniques are applied.
- **Glycosylation analysis**
  Comprehensive glycoprotein characterisation at the monosaccharide level complements existing detailed mapping of the amino acid sequence.
- **PEGylation analysis**
  Determination of major and minor PEG binding positions, including relative amounts attached to each site.
- **N-terminal (Edman) and C-terminal sequencing**
  Identification of the amino-and carboxy-terminal amino acids to confirm sequence and homogeneity.
- **Intact mass determination**
  Precise, absolute mass measurement using mass spectrometry.
- **Impurity profiling**
  Techniques used include nano HPLC, UPLC and Multiple/Selective reaction monitoring to provide sensitivity and highly specific measurements to detect and quantify compounds such as truncated fragments, deamidation and oxidation.
- **Aggregation analysis by analytical ultracentrifugation**
- **Circular dichroism, NMR & X-ray**
- **Amino acid analysis and more**

ICH guidelines (ICH Q6B) require that the proteins and polypeptides are comprehensively characterised using an appropriate set of analytical procedures

## Proven biosimilars track record

**Proteomics International has attracted and maintained an array of blue chip international clients. The company has successfully undertaken many biosimilars projects including, but not limited to:**

- **Epidermal growth factor (EGF)**
- **Follicle stimulating hormone (h-FSH)**
- **Granulocyte colony-stimulating factor (GCSF)**
- **Human growth hormone (HGH)**
- **Insulin**
- **Immunoglobulin (IgG) Fab fragment**
- **Immunoglobulin (IgG) whole molecule**
- **Eptifibatide (cyclic peptide)**
- **Octreotide (cyclic peptide)**

Data packages have been used for regulatory submission in the USA, Europe, India and China

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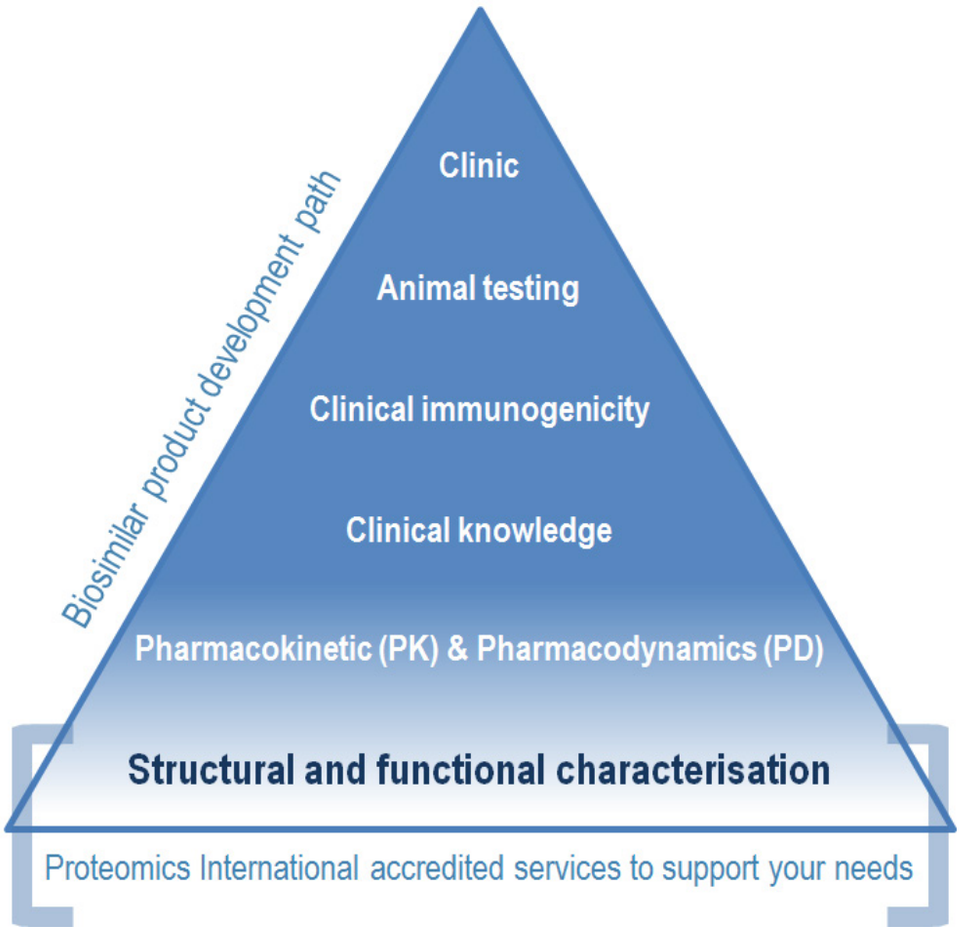


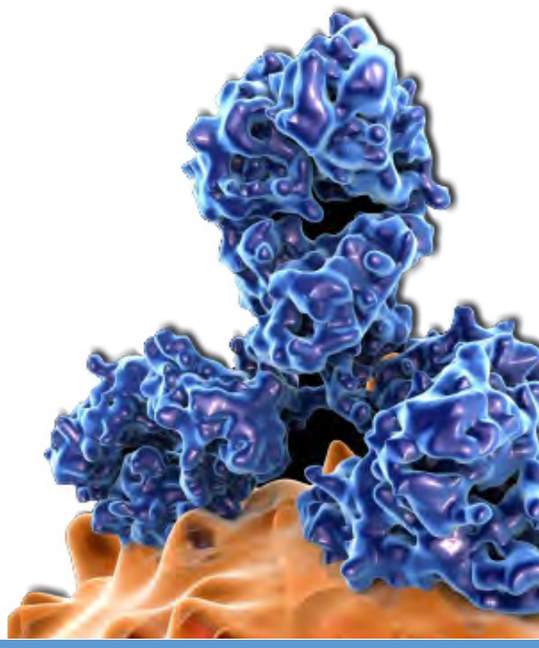

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